Testimony of Phillip A. Proger

Regarding "H.R. 1902, Protecting Consumer Access to Generic Drugs Act of 2007"

Before the United States House of Representatives Subcommittee on Commerce, Trade, and Consumer Protection of the Committee on Energy and Commerce

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Summary

In my testimony, I will address three principal questions that I believe underlie any effort to pass legislation. *First*, what is the nature and seriousness of the problem to which H.R. 1902 is addressed? *Second*, how does the proposed solution in H.R. 1902 relate to that problem? *Third*, what is the danger that unintended consequences will flow from the provisions of H.R. 1902 that could undermine its legislative intent?

I conclude (1) that reverse payments are not "reverse" and not always anticompetitive; (2) that the proposed solution is not a competitive solution at all, and is contrary to the historical role of Congress in enacting antitrust legislation and the FTC in conducting antitrust enforcement; and finally, (3) that adopting a broadly inclusive per se ban on any settlement "for value" will have unintended consequences that could actually inhibit incentives for generic entry, and may alter the balance between drug innovation and affordability that Hatch-Waxman currently embodies.

For all of these reasons, it is my view that issues raised by H.R. 1902 warrant further study. H.R. 1902 would adopt for the first time the blunt instrument of a per se antitrust rule against specific conduct in a specific industry. Such a step would be a departure for Congress, which has previously (and wisely) decreed that antitrust practices should be measured by *competitive* standards. That is, whether a given practice at a given time harms consumers by reducing output as a means of raising price. A per se ban on settlements which transfer "value" to the generic is neither needed, nor consistent with our well-developed system of antitrust jurisprudence. The FTC has demonstrated that it is an able and vigorous prosecutor in this area. Pursuant to the 2003 Medicare Act, all settlements must be notified to the FTC. Private class action plaintiffs also have challenged such settlements. Congress can be thus assured that all settlements between a patent holder and a generic challenger will be subject to complete scrutiny. The FTC and the courts can review each settlement — like any other agreement — and determine whether that agreement does in fact reduce competition.

Finally, I include in my discussion of unintended consequences a series of questions that I believe should be considered before this change is enacted.

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I. INTRODUCTION

Mr. Chairman and Members of the Committee, thank you for inviting me to express my views concerning H.R. 1902 and the issues it addresses.

I should note at the outset that, while I am a partner at Jones Day, my testimony today and my written submission are in my individual capacity, expressing the views that are my own and which do not necessarily represent the views of Jones Day, any other Jones Day partner, or any client of Jones Day. Jones Day is a large multinational law firm and it is possible that one or more Jones Day clients may have an interest in this legislation.

I commend the Chairman and Members of the Committee for its focus on this question. The American public has a critical interest in ensuring that the pharmaceutical industry continues to develop new and improved drugs at the lowest feasible cost. For a suffering patient, the invention of a new drug can be a miracle that literally saves lives just as the provision of such drugs at affordable prices may vastly improve those lives. In the Hatch-Waxman Act and elsewhere, Congress has heretofore achieved a judicious balance between the twin goals of drug innovation and drug affordability, a balance that does not permit one goal to undermine the other.

I also commend the Federal Trade Commission (FTC) for its leadership in this important area. Through both studies of industry experience and enforcement efforts, the FTC has called attention to the question of patent settlements' effect on competition.

The FTC's efforts have helped to emphasize a long-standing principle of antitrust law that settlement agreements that extend the exclusionary effect of a patent beyond that inherent in the patent grant tend to be anticompetitive. On this principle, courts have supported the FTC and those antitrust plaintiffs who echo their concerns. On the related but different question of whether so-called "reverse payments" in Hatch-Waxman settlements are anticompetitive even when the settlement is *not* beyond the scope of the patent, however, the FTC has failed to persuade those courts either (1) that the resulting effect they identify is an anticompetitive effect, or (2) that payments in settlements are always anticompetitive. That, in my view, is what has brought us together today.

In my testimony, I will address three principal questions that I believe underlie any effort to pass legislation. *First*, what is the nature and seriousness of the problem to which H.R. 1902 is addressed? *Second*, how does the proposed solution in H.R. 1902 relate to that problem? *Third*, what is the danger that unintended consequences will flow from the provisions of H.R. 1902 that could undermine its legislative intent?

I conclude (1) that reverse payments are not "reverse" and not always anticompetitive; (2) that the proposed solution is not a competitive solution at all, and is contrary to the historical role of Congress in enacting antitrust legislation and the FTC in conducting antitrust enforcement; and finally, (3) that adopting a broadly inclusive per se ban on any settlement "for value" will have unintended consequences that could actually inhibit incentives for generic entry, and may alter the balance between drug innovation and affordability that Hatch-Waxman currently embodies.

For all of these reasons, it is my view that issues raised by H.R. 1902 warrant further study. H.R. 1902 would adopt for the first time the blunt instrument of a per se antitrust rule against specific conduct in a specific industry. Such a step would be a departure for Congress, which has previously (and wisely) decreed that antitrust practices should be measured by *competitive* standards. That is, whether a given practice at a given time harms consumers by reducing output as a means of raising price. A per se ban on settlements which transfer "value" to the generic is neither needed, nor consistent with our well-developed system of antitrust jurisprudence. The FTC has demonstrated that it is an able and vigorous prosecutor in this area. Pursuant to the 2003 Medicare Act, all settlements must be notified to the FTC. Private class action plaintiffs also have challenged such settlements. Congress can be thus assured that all settlements between a patent holder and a generic challenger will be subject to complete scrutiny. The FTC and the courts can review each settlement — like any other agreement — and determine whether that agreement does in fact reduce competition.

Finally, I include in my discussion of unintended consequences a series of questions that I believe should be considered before this change is enacted.

II. WHAT IS THE NATURE AND DEGREE OF THE PROBLEM?

A. Is It A Hatch-Waxman Problem?

One of the concerns to which H.R. 1902 is addressed may be stated as follows: Unless Congress acts to place limits on the ability of ANDA litigants to settle, Hatch-Waxman's goal of ensuring generic competition will be frustrated. In my view, that concern does not warrant a special rule carving out these specific agreements from the antitrust laws.

The Hatch-Waxman Balance. As the official name of what we now call Hatch-Waxman reflects, the Drug Price Competition and Patent Term Restoration Act of 1984 (Hatch-Waxman Act),[1] facilitated market entry of lower-priced generic drugs while maintaining incentives to invest in new drug development. In the words of the Food and Drug Administration (FDA), "[t]he two parts of the [Hatch-Waxman Amendments] were intended to provide a careful balance between promoting competition among pioneer or brand-name and generic drugs, and encouraging research and innovation," through protection of patent rights.[2] Thus, the Act attempts to balance the twin goals of improved consumer welfare through innovation and invention and through lower cost drugs resulting from generic entry.

The Act contains provisions to facilitate generic entry. *First*, the Act allows generic manufacturers to piggy-back on the brand-name manufacturer's New Drug Application (NDA), where a patent holder must demonstrate the safety and efficacy of its product,[3] by allowing a generic manufacturer to simply file an Abbreviated New Drug Application (ANDA), demonstrating that its product is bioequivalent to the brand-name

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[1] Pub. L. No. 98-417, 98 Stat. 1585 (1984).

[2] 54 Fed. Reg. 28,872 (July 10, 1989) (proposed rule); *see also* 59 Fed. Reg. 50,338 (Oct. 3, 1994) (final rule) ("Congress intended the two titles [of the Hatch-Waxman Amendments] to provide a careful balance between promoting competition among brand-name and duplicate or 'generic' drugs and encouraging research and innovation."); *Abbott Labs. Inc. v. Young*, 920 F.2d 984, 985 (D.C. Cir. 1990) ("Facing the classic question of the appropriate trade-off between greater incentives for the invention of new products and greater affordability of those products, Congress struck a balance between expediting generic drug applications and protecting the interests of the original drug manufacturers.") (citing H.R. Rep. No. 98-857 (Pt. 1), at 14-15, *reprinted in* 1984 U.S.C.C.A.N 2647, 2648); *Mylan Pharmaceuticals, Inc. v. Shalala*, 81 F. Supp. 2d 30, 32 (D.D.C. 2000) ("[T]he Hatch-Waxman Amendments emerged from Congress' efforts to balance two conflicting policy objectives: to induce name-brand pharmaceutical firms to make the investments necessary to research and develop new drug products, while simultaneously enabling competitors to bring cheaper, generic copies of those drugs to market.") (internal quotation marks omitted).

[3] 21 U.S.C. § 355(b).

counterpart.[4] If the generic manufacturer seeks entry before the patent expires, it has the option of submitting an ANDA IV, which certifies that the listed patent "is invalid or will not be infringed by the manufacture, use, or sale of the [generic] drug."[5] *Second*, as an incentive to incur potentially substantial litigation costs, the first company to submit an ANDA IV is awarded a 180-day period of exclusive rights to market a generic formula of the pioneer drug before any other ANDA may be approved.[6]

The Act also contains provisions to encourage innovation and invention. *First*, the filing of an ANDA IV creates an automatic cause of action for patent infringement, and the applicant must notify the owner of the listed patent of the filing of its ANDA IV certification.[7] *Second*, the patent holder has 45 days to initiate a patent infringement suit against the ANDA applicant,[8] and, if it does so, the FDA's approval is automatically stayed for 30 months, unless the patent expires or is judicially determined to be invalid or not infringed before that time.[9] *Third*, the Act gives patent holders the ability to extend the life of a patent to compensate for the fact that patent exclusivity includes the time when a drug is under FDA review and thus not yet on the market.[10] Yet another provision grants an additional three years of market exclusivity when the brand can obtain an approval requiring clinical tests, such as a new dosage form.[11]

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[4] *Id.* § 355(j).

[5] *Id*. § 355(j)(2)(A)(vii); *see also* 21 C.F.R. § 314.94(a)(12)(A)(4).

[6] *Id.* § 355(j)(5)(B)(iv).

[7] *Id*. § 355(j)(2)(B).

[8] *Id*. § 355(j)(5)(B)(iii).

[9] *Id.*

[10] Congressional Budget Office (CBO), "How Increased Competition from Generic Drugs has affected Prices and Returns in the Pharmaceutical Industry," ix, xii, xiv (July 1998) (CBO).

[11] CBO, at xiv.

In striking this balance, the Act's legislative history further confirms that (1) the Hatch-Waxman Amendments were not intended to override the statutory presumption of patent validity under 35 U.S.C. § 282;[12] (2) the Amendments were not intended to legalize the marketing of infringing drugs;[13] and (3) the Amendments, including the provisions relating to the 30-months stay, were not intended to authorize infringing entry.[14] Nor is there any indication that, in establishing procedures to encourage litigation between NDA holders and ANDA filers, Congress intended to deprive such parties of the same rights to settle such litigation enjoyed by all other litigants.

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[12] *See* H.R. Rep. No. 98-857, pt. 1, at 27, *reprinted in* 1984 U.S.C.C.A.N. at 2661 ("The provisions of this bill relating to the litigation of disputes involving patent validity and infringement *are not intended to modify existing patent law* with respect to the burden of proof and the nature of the proof to be considered by the courts *in determining whether a patent is valid or infringed*.") (emphasis added); *see also id*. ("Concern has been expressed that permitting an applicant to market its drug at the conclusion of the 18 month period and possibly before the resolution of the patent infringement suit overturns the statutory presumption of a patent's validity. *On the contrary, the Committee intends that a patent would have the same statutory presumption of validity as is afforded under current law*.") (emphasis added).

[13] *See, e.g*., *id.*, *reprinted in* 1984 U.S.C.C.A.N. at 2678 ("Section 271(e)(1) provides that it shall not be an act of infringement to make, use, or sell a patented invention solely for uses reasonably related to the development and submission of information under a federal law which regulates the approval of drugs. This section *does not permit the commercial sale of a patented drug* by the party using the drug to develop such information, but it does permit the commercial sale of research quantities of active ingredients to such party. . . . The purpose of sections 271(e)(1) and (2) is to establish that experimentation with a patented drug product, when the purpose is *to prepare for commercial activity which will begin after a valid patent expires, is not a patent infringement*.") (emphasis added).

[14] *See id*., *reprinted in* 1984 U.S.C.C.A.N. at 2679 ("In the event the patent is found to be valid and infringed, so that the act of infringement described in section 271(e)(2) has occurred, the remedies available to the court are three-fold. . . . If the infringing party has begun commercial marketing of the drug, *damages and other monetary relief and injunctive relief may be awarded for the infringement and to prevent further infringement*. In addition, the FDA would be mandated to change the effective date of the approved ANDA to the expiration date of the infringed patent.") (emphasis added); H.R. Rep. No. 98-857, pt. 2, at 9 (1984), *reprinted in* 1984 U.S.C.C.A.N. 2686, 2693 (explaining reasons for rejection of proposed amendment to House bill replacing determinate stay of FDA approval with final decision by district court and noting that "[t]his provision was added by the Committee on Energy and Commerce to accommodate the competing concerns of the [Pharmaceutical Manufacturers Association ("PMA")] and the generic manufacturers. The PMA was willing to compromise on the provisions of title I of the bill (relating to abbreviated new drug application procedures (ANDAs)) in exchange for some *greater protection* of existing human pharmaceutical patents.") (emphasis added).

Payments are "Natural." One "natural byproduct" of Hatch-Waxman's structure and incentives is the resulting focus on reverse payments.[15] Because Hatch-Waxman gives a generic challenger the opportunity to obtain a declaratory judgment against the patent without risking liability for damages, the generic has everything to gain while the patent holder has everything to lose. As courts and commentators have explained, such cases can only be settled by the transfer of value from the patent holder to the generic challenger, who (in the words of Judge Posner) "would not settle unless he had something to show for it."[16] In cases outside the Hatch-Waxman context, on the other hand, the transfer of value to the patent challenger may take other forms than cash, because the alleged infringer is already in the market place taking sales away from the patent holder, and thus exposing itself to damages. In those cases, the transfer of value may take the form of a compromise of the infringement damages already inflicted, or restrictions on the existing infringing sales in terms of time, geography, or royalty rate. In Hatch-Waxman cases, however, none of those infringing sales have occurred, and all of the risk beyond legal fees lies with the patent holder. That is why it is "natural" for the value flowing to the challenger to take its most efficient form, cash.

But this difference is one of form only. In the words of one of the drafters of the FTC and United States Department of Justice guidelines for the enforcement of intellectual property: "Hatch-Waxman creates a context in which payments from the patent owner to the infringer become explicit rather than implicit, but it does not change

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[15] *In re Ciprofloxacin Hydrochloride Antitrust Litigation (Cipro)*, 261 F. Supp. 2d 188, 252 (E.D.N.Y. 2003).

[16] *Asahi Glass Co. Ltd., Inc. v. Pentech Pharms, Inc.*, 289 F.Supp. 2d 986, 994 (N.D. Ill. 2003) (Posner, J., sitting by designation).

the underlying nature of the payments or make them more anticompetitive than such payments in the traditional context."[17]

If there were any doubt that this is true, one should ask this question: Why are there no examples of patent settlement "pay-offs" in other industries? It makes just as much sense for a patent holder to pay a challenger to drop its case against a weak patent in other industries, so why does it not happen? The answer is that all settlements consist of transfers of value between parties based on their perceived risk of prevailing in the litigation,[18] and what each has economically at risk. Generally, economic value will flow from the party with greater risk to the party with lesser risk. Hatch-Waxman settlements are not different in economic terms, nor of greater concern in their effect on consumers.

The Success of Hatch-Waxman. The failure of Hatch-Waxman to place limits on the rights of ANDA litigants to settle has not undermined the goals of the Act.

The evidence shows that the Act's goal of facilitating generic entry has been realized. *First*, in 1984, prior to the enactment of Hatch-Waxman, the generic drug share of the U.S. prescription market was 19%. In 2006, it was 61%.[19] (*See* Appendix A.) The generic share of the prescription drug market grew steadily at a rate of roughly two percent per year from 1984 to 2006, first exceeding 50 percent in 1998. (*See* Appendix B.) Industry analysts expect further growth in the share of generic

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[17] Kent S. Bernard & Willard K. Tom, *Antitrust Treatment of Pharmaceutical Patent Settlements: The Need for Context and Fidelity to First Principles*, 15 FED. CIR. B.J. 617, 621 (2006).

[18] *See Cipro*, 261 F. Supp. 2d at 251.

[19] Deutsche Bank, "Global Pharmaceuticals – Pharmaceuticals for Beginners," at 65 (Aug. 2005); Credit Suisse, "Sector Review – What's New in Generics," at 4 (Mar. 2007).

prescriptions in the next few years as several large drugs face patent expiration.[20] *Second*, Hatch-Waxman increased the proportion of branded drugs that face generic competition. In 1983, only 35 percent of the top-selling drugs with expired patents had generic versions available, while nearly all do today.[21] *Third*, Hatch-Waxman reduced the average delay between patent expiration and generic entry from more than three years to less than three months for top-selling drugs.[22]

The growth and success of the generic drug industry has resulted in lower prices not only for blockbuster drugs, but virtually for all consumer drugs. While roughly 80 percent of drugs with sales of more than $100 million face generic competition, and do so within 50 days of their patents expiring, around 50 to 60 percent of drugs with sales in the $10 to $25 million range face generic competition 200 days after their patents expire.[23]

Some critics of reverse payments argue that Hatch-Waxman has achieved its remarkable success in increasing the availability of generic drugs *despite* its failure to limit the rights of litigants to settle. But others, including some judges, economists, antitrust experts, and those who run generic companies, disagree. They suggest, to the contrary, that the knowledge that generic challengers possess the same rights as litigants in every other industry to settle cases is a key factor in the incentive to bring

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[20] Deutsche Bank, at 65; Danske Equities, "Sector Report - Pharmaceuticals and Biotech," at 13 (Oct. 2005); Credit Suisse, at 4.

[21] Congressional Budget Office (CBO), "How Increased Competition from Generic Drugs has affected Prices and Returns in the Pharmaceutical Industry," July 1998: xii (excluding antibiotics and drugs approved before 1962).

[22] CBO, at ix.

[23] Deutsche Bank, at 65-66.

Paragraph IV challenges in the first place.[24] For precisely that reason, Judge Posner has observed, in words that directly apply to the text of H.R. 1902, that:

> "Reverse payment" patent settlements . . . are criticized and sometimes invalidated on the theory that they prevent competition. Whether it is a sound theory may be doubted, since if settlement negotiations fell through and the patentee went on to win his suit, competition would be prevented to the same extent. *A ban on reverse-payment settlements would reduce the incentive to challenge patents by reducing the challenger's settlement options should he be sued for infringement, and so might well be thought anticompetitive.*[25]

In sum, both the evidence of actual generic entry and the incentives of ANDA filers signal caution.

An important question for the Committee is whether the ability of ANDA litigants to settle cases has *increased* the number of generic challenges and resulted in a net benefit to consumers. A related, and equally important question, is whether placing severe limitations on settlement rights will hurt both the generic challengers *and* patent holders. A ban on settlements may upset the delicate balance that Hatch-Waxman has heretofore maintained, which is to promote generic entry while protecting legitimate patent rights.

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[24] *Cipro*, 261 F. Supp. 2d at 256 ("The incentives created by the Hatch-Waxman Amendments have led to generic investment in product development, patent review and product challenges through litigation. Indeed, Barr has admitted that it has over ten ANDA challenges in litigation today and more than twice that number under review. To maximize these incentives, a generic company should be permitted to choose not only when to commence patent litigation, but also when to terminate it. Otherwise, the incentives to mount an ANDA IV challenge could be reduced.") (internal citation omitted); *see also Paying Off Generics to Prevent Competition With Brand Name Drugs: Should It Be Prohibited?*, *Before the S. Comm. on the Judiciary*, *available at* http://judiciary.senate.gov/testimony.cfm?id=2472&wit_id=5984 (testimony of Bruce L. Downey, Chairman and CEO, Barr Pharmaceuticals, Inc., Jan. 17, 2007) ("The proposed legislation [] would stifle a generic company's ability to resolve patent disputes . . . . The simple fact is that, in some instances, litigation settlements turn out to be the means by which consumers gain access to generic drugs before patent expiration. Indeed, patent litigation settlements are the sole means by which the public can be guaranteed generic access prior to patent expiration.").

[25] *Asahi Glass*, 289 F. Supp. 2d at 994 (citations omitted; emphasis added).

Our Society also benefits from new and improved drugs. The time and expense of developing new life-saving drugs continues to spiral. The estimated cost of bringing a new drug to market reportedly rose from $231 million in 1997 to $802 million in 2000. And even those who argue that the importance of patent protection to innovation is overstated recognize its continued importance in this industry. Only last week, FTC Commissioner Rosch cited an economist whose data allegedly reflected "almost no relationship [between innovation and patent protection], *except* in the pharmaceutical industry."[26]

If we agree that "patent protection is important in spurring innovation in the pharmaceutical industry,"[27] and further acknowledge Hatch-Waxman's success in achieving generic entry, we might well conclude that making a fundamental shift in the existing rights of Hatch-Waxman litigants raises all the dangers of fixing a "problem" that is not a problem at all. As discussed below, under these circumstances it would be appropriate to allow the natural evolution of the law here to continue.

B. What Is The Scope of The Problem?

The Generic "Success Rate." Those who favor severe limits of settlement rights often base their concern on the so-called generic success rate under Hatch-Waxman. Some have read the FTC's 2002 Generic Drug Study as establishing that, of all Hatch-Waxman lawsuits initiated against ANDA IV filers from 1992 and 2002, the

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[26] Remarks of J. Thomas Rosch, FTC Commissioner, Law Seminars International, Pharmaceutical Antitrust, Washington, D.C. (April 26, 2007), at 1-2 (citing F.M. Scherer, "The Political Economy of Patent Policy Reform in the United States," Working Paper 06-22, Oct. 2006, AEI-Brookings Joint Center for Regulatory Studies, at 6, *available at* http://www.aei.brookings.org/admin/authorpdfs/page.php?id=1334) (emphasis added).

[27] *Id*. at 2.

generic challenger prevailed 73% of the time.[28] But, the 2002 Study makes no such claim.[29] Indeed, the Study demonstrates that for all cases in which the patent holder sued the first ANDA IV challenger, the generic prevailed only 29.33% of the time.[30] The number for *all* ANDA IV cases (*i.e.*, against both first filers and later filers) cannot be determined precisely from the Study itself, but appears to be even lower, that is, no greater than 24.75%.[31]

The 73% figure was obtained by focusing on a much smaller universe of ANDA cases. That smaller number was derived by subtracting from all cases initiated against ANDA IV filers (1) those not yet resolved at the time of the Study, (2) those that were settled, (3) those for which the patent expired before resolution, (4) those for which the patent was withdrawn, and, finally, (5) those which duplicated the result for the same patent (*e.g.*, where the patentee won several challenges to the same patent, as in *Tamoxifen* and *Ciprofloxacin*).[32] Thus, the 73% figure derives from 29 generic victories,

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[28] *See* Petition for Writ of Certiorari, *F.T.C. v. Schering-Plough Corp*., 402 F.3d 1056 (11th Cir. 2005) (No. 04-10688), 2005 WL 2105243 at *5 (citing Federal Trade Commission, *Generic Drug Entry Prior to Patent Expiration: An FTC Study*, at 19-20 (July 2002), *available at* www.ftc.gov/os/2002/07/genericdrugstudy.pdf); Brief of Amicus Curiae Federal Trade Commission in Support of Plaintiffs-Appellants, *In re Tamoxifen Citrate Antitrust Litigation,* 466 F.3d 187 (2nd Cir. 2005) (No. 03-7641), 2005 WL 3332374 at *7 n.10; *Prepared Statement of the Federal Trade Commission, Before the Special Committee on Aging of the United States Senate, on Barriers to Generic Entry*, *available at*, http://ftc.gov/os/2006/07/P052103BarrierstoGenericEntryTestimonySenate07202006.pdf; *Prepared Statement of the Federal Trade Commission, Before the Committee on the Judiciary of the United States Senate on Anticompetitive Patent Settlements in the Pharmaceutical Industry: The Benefits of a Legislative Solution*, *available at*, http://ftc.gov/speeches/leibowitz/070117anticompetitivepatentsettlements_senate.pdf.

[29] 2002 FTC Study at 19-20.

[30] *Id.* at 14-17 (22 generic victories out of 75 cases initiated against first filers).

[31] *Id.* at 18-20 (29 generic victories out of at least 118 ANDA cases initiated, *i.e.*, 75 (p. 14) plus 43 (p. 18)).

[32] The first four of these subtractions are set forth clearly in the chart on page 15 of the FTC Study. The last subtraction, eliminating "similar outcomes" is referenced on page 19 in calculating the overall success rate.

divided by a total of 40 cases in which there were final judicial determinations of the patent claim.

Whatever their significance, the numbers in the 2002 Study involved samples too small to support a conclusion that generics have and always will have a high success rate.[33] Thus, even an accurately reported generic success rate of 24% or 29% tells us little, especially when we consider that ANDA IV litigation involves a pre-selection by generic applicants of those patents most vulnerable to challenge. Nor should any *average* success rate serve to render problematic any individual settlement involving a patent which, by its terms, excluded all generic entry and was repeatedly upheld in court. For current purposes, however, the Committee may rest easy that there is no empirical support for the view that three out of four, or even a bare majority of, patent settlements somehow deprive consumers of a generic victory.

The Court Decisions. Nor do the cases actually decided reflect any significant consumer harm. Consider first the cases in which courts rejected the view that generic drug settlements are anticompetitive. In the *Tamoxifen* and *Ciprofloxacin*[34] cases, the patents were compound patents on the drug's active ingredient that precluded, by definition, all generic competition.[35] There was no dispute that the patents, if valid, would have been infringed by the generic product. In both cases, moreover, the patent was repeatedly upheld against validity challenges after the settlement. In *Tamoxifen*,

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[33] In fact, one commentator has concluded that patent holders were winning more cases after publication of the FTC study. Gregory Glass, *Why Settle?*, Update, Sept./Oct. 2005, at 17-18 ("When settlements decreased after the FTC study, [] brand companies won 40% of the cases filed (and 53% of those cases actually tried).").

[34] I am one of the counsel for the patent holder in these cases.

[35] *See In re Tamoxifen Citrate Antitrust Litigation (Tamoxifen)*, 466 F.3d 187, 214 (2d. Cir. 2006), *pet. for cert. filed*, 75 U.S.L.W. 3333 (Dec. 13, 2006) (06-830); *Cipro*, 261 F. Supp. 2d at 197.

three generic companies filed ANDA IVs for tamoxifen and mounted challenges to the patent similar to the challenge raised originally by the first-filer. One challenge was dismissed by consent when the generic agreed that FDA approval would not be effective before the expiration of the patent,[36] and two federal courts, one appellate and one district, concluded that the patent was, in fact, valid.[37]

In *Ciprofloxacin,* moreover, the patent holder after the settlement voluntarily submitted its patent to the PTO for a successful reexamination, after which four generic companies filed ANDA IVs. One challenge was dismissed,[38] and the patent holder won the other three.[39]

And now consider the two cases — *Cardizem* and *Terazosin* — in which antitrust liability has been imposed on settlements that those courts found to go beyond the scope of the formulation patents at issue. The courts found that the "interim" settlements precluded not only infringing generics but non-infringing ones as well.[40]

Yet, in *Cardizem*, it was also shown that, as soon as the generic produced a non-infringing formulation and obtained FDA approval, the "interim" settlement agreement

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[36] *AstraZeneca UK Ltd. v. Mylan Pharms., Inc.*, No. 00-2239, slip op. at 2-3 (W.D. Pa. Nov. 30, 2000).

[37] *See Zeneca Ltd. v. Novopharm Ltd.*, 111 F.3d 144, 146 (Fed. Cir. 1997) (deciding that Zeneca's patent was valid); *Zeneca Ltd. v. Pharmachemie B.V.*, No. 96-12413, 2000 WL 34335805, at *15 (D. Mass. Sept. 11, 2000) (concluding that Zeneca had not engaged in inequitable conduct and that the patent was valid). *See generally Tamoxifen*, 466 F.3d at 204.

[38] *See Bayer AG v. Ranbaxy Pharms., Inc.*, No. 3:98 Civ. 4464 (D.N.J. Oct. 29, 1999) (dismissing case per stipulation).

[39] *See Bayer AG v. Schein Pharm., Inc.*, 301 F.3d 1306 (Fed. Cir. 2002). *See generally Cipro*, 261 F. Supp. 2d at 197.

[40] *In re Cardizem CD Antitrust Litigation*, 105 F. Supp. 2d 682 (E.D. Mich. 2000) (where the patent covered only a once-a-day timerelease delivery and its dissolution profile); *In re Terazosin Hydrochloride Antitrust Litigation*, 164 F. Supp. 2d 1340 (S.D. Fla. 2000) (where the patent covered only the tablet formulation of the drug).

was terminated, allowing generic entry.[41] Thus, in announcing its Consent Decree with the parties, the FTC stated that "it does not appear that there was any delay in the entry into the market of a generic version of Cardizem CD by Andrx or any other potential manufacturer, or that the conduct or agreement at issue delayed consumer access to a generic version of Cardizem CD."[42]

Similarly, on remand from the Eleventh Circuit's reversal in *Terazosin*, the District Court held again that a portion of the settlement agreement was per se illegal, that is, the portion in which the generic agreed not to enter in the period between a generic victory at trial and an affirmance of that victory on appeal.[43] (The Court's per se ruling was unrelated to the existence of reverse payments.) In a subsequent trial, however, a jury awarded zero damages to the antitrust plaintiff, concluding that the generic company would not have entered the market "at risk" while the appeal was pending.[44]

In sum, whether one agrees or disagrees with the fine points of the antitrust analysis in these decisions, it is difficult to argue as a matter of fact that they have deprived the American consumer of access to any non-infringing generic drug. As these cases illustrate, moreover, antitrust enforcement is working well.

C. Is There an Antitrust Problem?

Patent settlements can harm competition. Any settlement that excludes more competition than would the patent itself is likely to be anticompetitive, because it obtains

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[41] *Cardizem*, 105 F.Supp. 2d at 688-89.

[42] *See* www.ftc.gov/os/2001/04/hoechstanalysis.pdf.

[43] *Terazosin*, 352 F.Supp. 2d at 1319.

[44] *Kaiser Foundation Health Plan, Inc. v. Abbot Labs. & Geneva Pharmaceuticals, Inc.*, No. 2:02-cv-02443 (C.D. Cal. Apr. 6, 2006), *appeal docketed*, Nos. 06-55687, 0655748 (9th Cir. May, 8, 2006).

by agreement an exclusionary effect that even in victory the patent holder would not have obtained.

A different question is whether a settlement is anticompetitive when it excludes no competition beyond the scope of the patent. On this question, plaintiffs have been notably unsuccessful in persuading courts that the presence of payments in such settlements is, in fact or theory, anticompetitive. Courts have considered the claims that such settlements are "pay offs" to horizontal competitors to "exit" the market and thus constitute per se illegal market division. In response, courts have observed that (1) all settlements can be labeled "pay offs" to avoid litigation risk;[45] (2) all patent litigation, by its nature, seeks to "delay" entry in the form of the challenger's infringing entry;[46] (3) all patent agreements, including the most common license, would be per se illegal market division if one were to ignore the existence of the patent;[47] and (4) the antitrust law does not protect infringing entry, which in fact injures consumers.[48] For these reasons, courts have concluded that plaintiffs have focused on the wrong villain:

> If [the patent holder] Abbott had a lawful right to exclude competitors, it is not obvious that competition was limited more than that lawful degree by paying potential competitors for their exit. *The failure to produce the competing terazosin drug, rather than the payment of money, is the exclusionary effect*, and litigation is a much more costly mechanism to achieve exclusion, both to the parties and to the public, than is settlement.[49]

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[45] *See, e.g.*, *Asahi Glass*, 289 F. Supp. 2d at 994.

[46] *See, e.g.*, *Valley Drug Co. v. Geneva Pharmaceuticals, Inc*., 344 F.3d 1294, 1310 (11th Cir. 2003).

[47] *See, e.g.*, *Valley Drug*, 344 F.3d at 1304; XII Phillip E. Areeda & Herbert Hovenkamp, ANTITRUST LAW, ¶ 2040b, at 199 (1999).

[48] *See, e.g.*, *SCM Corp. v. Xerox Corp*., 645 F.2d 1195, 1204 (2d Cir. 1981); *Rubber Tire Wheel Co. v. Milwaukee Rubber Works Co*., 154 F. 358, 364 (7th Cir. 1907).

[49] *Valley Drug*, 344 F.3d at 1309 (citation omitted) (emphasis added).

Courts have further noted the plaintiffs' failure to tie the presence of payments to any real anticompetitive effect by pointing out that the same allegedly harmful effect to consumers could be accomplished by settlements with licenses, depending on their terms, even though the plaintiffs insist that licenses are competitively benign.[50] As one court observed: "Thus, outlawing exclusion-payment settlements in favor of early-entry licenses would not necessarily result in a public benefit, or satisfy plaintiffs, unless royalty rates are also constrained."[51]

In my view, the emerging consensus among these courts leads to this conclusion: If you want to challenge a patent infringement settlement, you must show that it goes beyond the scope of the patent, and you can do that in two ways: *First*, you can show that it excludes non-infringing goods without competitive justification. *Second*, you can show that the patent is so weak with respect to the alleged infringing product that it has no scope at all. That leads to the objectively baseless test of Judge Posner, which holds, in essence, that if the patentee had a colorable enough patent claim to bring the infringement action, then it had the right to settle within the exclusionary effect of the patent.[52]

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[50] *See Cipro*, 261 F. Supp. 2d at 252 ("In fact, even in the traditional context, implicit consideration flows from the patent holder to the alleged infringer. For instance, suppose a case is ready for trial and the patent holder can prove damages (infringing sales) of $100 million. The parties settle before trial with the alleged infringer paying the patent holder $40 million and agreeing to cease sales of its product. In addition to the $40 million payment to the patent holder, there is an implicit $60 million payment to the alleged infringer to cease its sales. In reality, what has occurred is the alleged infringer is permitted to keep a portion of the profits from its sales. Under plaintiffs' analysis, a settlement such as this, where the patent holder forgoes collecting all damages due, would be a per se violation. Such a rule would discourage any rational party from settling a patent case because it would be an invitation to antitrust litigation.").

[51] *Cipro,* 363 F.Supp. 2d at 538.

[52] *Asahi Glass*, 289 F. Supp. at 994.

Contrary to the complaints of some, these courts have not ruled that patent law somehow trumps antitrust law in all cases. Rather, they have recognized that patents have long-term pro competitive effects that antitrust law embraces. This makes sense. Patent law traces its roots to the Constitution itself and existed long before the antitrust laws were passed. For the past 117 years, the courts have worked to apply antitrust law to patent agreements in a manner that respects the trade-off between a patent's short-term exclusion of rivalry and its long-term enhancement of consumer welfare through innovation and invention.

III. DOES THE PROPOSED SOLUTION SPEAK TO THE PROBLEM?

Even if the problem addressed by H.R. 1902 were one of genuine competitive restraint, the solution proposed — a flat, bright-line ban on any settlement in which a generic applicant receives "anything of value" from the patent-holder — would not be a competitive solution at all. Competitive analysis in antitrust is a fact-specific, detail driven assessment of actual consequences to markets and consumer welfare. It results in a fact-finder determining whether a given practice in a specific context does or does not reduce output and thus harm competition. In this context, the bright line rule of per se liability is too blunt an instrument to address factually-complex settlements involving different types of patents and different compromise points.

In its opinion in *Schering–Plough* the FTC derided a per se ban on patent settlements with payments as unsophisticated.[53] Shortly thereafter, it informed the

[53] In describing what it viewed as the *Cardizem* opinion's use of a per se rule, the Commission stated that it did not "believe the opinion has taken adequate account of Supreme Court decisions that mandate a more nuanced approach." *In the Matter of Schering-Plough Corporation*, No. 9297, 2003 WL 22989651, at *13, n.26 (F.T.C.) (Dec. 8, 2003). The Commission went on to hold that "we are not now prepared to say that all such payments should be viewed as per se illegal or 'inherently suspect.'" *Id.*

Supreme Court that, if the Sixth Circuit's decision in *Cardizem* were read to be a per se rule against reverse payments, that decision would be "erroneous."[54] The Committee should thus be exceedingly cautious in considering enacting such a per se ban by statute.

It is well established that the genius of antitrust law is its common law model, where the legality of particular conduct is assessed in light of the facts of the market, the industry, the product, and evolving standards of economic knowledge. Thus, one set of actions at a given time in a given market may be anticompetitive, but under different circumstances, the very same conduct may be procompetitive. As the Supreme Court has explained, "recognizing and adapting to changed circumstances and the lessons of accumulated experience" is an essential element of antitrust law.[55] Thus, the Supreme Court has repeatedly relied on and emphasized "the accepted view that Congress expected the courts to give shape to the statute's broad mandate by drawing on common-law tradition." *Id*. (emphasis added). Accordingly, the term "restraint of trade," as used in Section 1, "invokes the common law itself, and not merely the static content that the common law had assigned to the term in 1890." *Id*.

Consistent with this understanding, Congress has not traditionally decreed conduct unlawful per se. Rather, Congress has adopted competitive solutions to competitive problems, directing the courts and enforcers to focus on real-life effects of the allegedly anticompetitive conduct in evaluating its legality. Even Clayton Act

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[54] Brief for the United States as *Amicus Curiae* at 7, *Andrx Pharms. Inc. v. Kroger Co.*, 125 S. Ct. 307 (2004) (No. 03-779).

[55] *State Oil Co. v. Khan*, 522 U.S. 3, 20-21 (1997).

strictures on types of conduct (such as tying) depend on an ultimate finding of reduced competition in fact.[56]

It is arguably ironic for Congress to be adopting a per se ban on a specific industry practice when the Supreme Court has itself in recent years been moving away from strict presumptions about parties' economic behavior for antitrust purposes. The Supreme Court has increasingly eschewed the inflexibility of the per se label, which requires no inquiry into the competitive effects of the condemned practice.[57] That default approach is the rule of reason, which entails scrutinizing parties' conduct by carefully considering the possible benefits and harms to competition resulting from an alleged restraint.[58] Accordingly, the Supreme Court has rejected many of its previously adopted per se rules in recent years, including two in the last term.[59]

Regulation of safe harbors by the FTC, as provided in Section 3 of the Bill, will not help. I have always understood the FTC to think of itself as an enforcer, rather than

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[56] *See* 15 U.S.C. § 14 ("It shall be unlawful for any person engaged in commerce, in the course of such commerce, to lease or make a sale or contract for sale of goods, wares, merchandise, machinery, supplies, or other commodities, . . . where *the effect* of such lease, sale, or contract for sale or such condition, agreement, or understanding may be *to substantially lessen competition* or tend to create a monopoly in any line of commerce.") (emphasis added).

[57] *See Broadcast Music, Inc. v. CBS*, 441 U.S. 1, 7-8 (1979) ("[This] Court has held that certain agreements or practices are so plainly anticompetitive … and so often lack … any redeeming virtue, … that they are conclusively presumed illegal without further examination under the rule of reason generally applied in Sherman Act cases.") (internal citations omitted). A practice historically be condemned as per se anticompetitive when "the practice facially appears to be one that would always or almost always tend to restrict competition and decrease output." *Id.* at 19-20.

[58] *See, e.g., Business Elecs. v. Sharp Elecs. Corp.*, 485 U.S. 717, 723 (1988) ("Ordinarily, whether particular concerted action violates § 1 of the Sherman Act is determined through case-by-case application of the so-called rule of reason.").

[59] *See Continental T.V., Inc. v. GTE Sylvania Inc.*, 433 U.S. 36, 47-49 (1977), *overruling United States v. Arnold, Schwinn & Co*., 388 U.S. 365 (1967) (vertical non-price restrictions); *see also State Oil Co. v. Kahn*, 522 U.S. 3 (1997), *overruling Albrecht v. Herald Co.*, 390 U.S. 145 (1968) (maximum vertical price-fixing); *Illinois Tool Works Inc. v. Independent Ink, Inc*., 126 S. Ct. 1281 (2006) (presumption of market power in per se tying cases); *Texaco Inc. v. Dagher*, 126 S. Ct. 1276, 1279 (2006) (per se price-fixing in joint venture).

a regulatory agency, with respect to antitrust and unfair competition. The FTC already does, and can continue to, provide guidance through its decisions, transparency when it exercises prosecutorial discretion, speeches, and possibly enforcement guidelines. But they are called guidelines for a reason. The agencies recognize that individual facts in individual cases are what determines antitrust analysis.

Thus, if Congress perceives that settlements with payments are anticompetitive, the Congress should enact a competitive solution. If it is a patent law problem, such as there are too many drug patents (a conclusion for which I am unaware of existing support), then the House should marshal the evidence and amend the patent laws. If the problem somehow lies in Hatch-Waxman, despite its phenomenal success at introducing generic drugs, the House should marshal that evidence as well and amend Hatch-Waxman.[60] But introducing the first per se ban on a specific practice in a specific industry is, in my view, unwise.

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[60] New arguments against payments by Professor Hemphill and others are based on the existence of Hatch-Waxman. *See, e.g.*, C. Scott Hemphill, *Paying for Delay: Pharmaceutical Patent Settlement As a Regulatory Design Problem*, 81 N.Y.U. L. REV. 1553 (2006). The idea is that Hatch-Waxman creates incentives for later filers to free-ride on the efforts of the first filer. Thus, according to the critics, Hatch-Waxman changed the antitrust laws by implication, making anticompetitive a settlement that would not be anticompetitive in another industry. *Cf*. Remarks of J. Thomas Rosch, FTC Commissioner, Law Seminars International, Pharmaceutical Antitrust, Washington, D.C. (April 26, 2007), at 10 ("Thus, outside of the [Hatch-Waxman] context, I think the *Schering* and *Tamoxifen* decisions might be relatively uncontroversial."). Besides the fact that this argument would apply to all settlements with first-filers, with or without payments, there is another fundamental problem. It turns the Supreme Court's reasoning in *Verizon Communications, Inc. v. Law Offices of Curtis v. Trinko*, 540 U.S. 398, 415-16 (2004), on its head. There the Court made it clear that just because a federal regulatory scheme brought the parties together and created a federally mandated form of rivalry, that did not change the application of the antitrust laws to their behavior. There, the FCC mandate that the defendant cooperate with a competitor did not render its failure to do so, though a violation of communications law, an antitrust violation as well. *Id*. ("The Sherman Act is indeed the Magna Carta of free enterprise, but it does not give judges *carte blanche* to insist that a monopolist alter its way of doing business whenever some other approach might yield greater competition."). Other statutes may impliedly *repeal* the antitrust laws, but they never impliedly supplement them.

In fact, a competitive solution to any concern with Hatch-Waxman settlements already exists, in my view, with the FTC in its customary and leading rule. The Medicare Modernization Act of 2003 gave the FTC the notification its sought of ANDA settlements, so none will slip by unnoticed. The FTC retains its power to investigate fully, to file complaints when appropriate, to adjudicate those cases before the full Commission, and to defend its decisions in the courts. Private litigants have also brought antitrust cases attacking settlements, and show no apparent lack of interest in continuing. Courts, as indicated, have found some settlements illegal, others not, and are developing a body of rules. This normal evolution and reasoned elaboration of antitrust principles in this area should be preferred. It is consistent with how Congress treats other conduct in other industries, and in the FTC we have an able prosecutor.

IV. UNINTENDED CONSEQUENCES.

Even if The House views the problem as significant and the solution as appropriate, will there be unintended consequences from the Act as drafted? One obvious concern is whether H.R. 1902 will reduce the number of ANDA IV settlements. I think the answer is clear. After the FTC made clear that it would challenge payments, the total number of Hatch-Waxman settlements dropped. However, after courts in *Valley Drug*, *Ciprofloxacin*, *Schering Plough*, and *Tamoxifen* declined to impose per se liability on such settlements and concluded that so long as they constrain no more competition than protected by the patent, settlements with payments are not suspect,

such settlements rose again sharply. Thus, a presumptive rule against payments clearly means *fewer* settlements.[61]

The proposed Bill's use of the term "Anything of Value" means that it condemns every settlement, except for a narrow exception provided in Section 2(b), because all settlements transfer value. As the Bill is written, the exchange of "value" does not even have to be causally connected to the settlement of the patent claim. Any cross-license or co-promotion agreement would be banned. Allowing the challenger to enter early as an authorized generic would also be banned. The only thing allowed is free entry with the generic described in the ANDA—*i.e*., no license restrictions of any kind—at a date prior to expiration. That will greatly reduce settlements because the Hatch-Waxman parties value added time on entry differently. Thus if the generic insists on two more months to get another $5 million in profit, and the brand will not agree because, while willing to pay $5 million in cash, the two months would cost it $30 million, there will be

[61] The FTC Reports indicate that in 2004, there were 0 agreements with restriction on generic entry and compensation to the generic out of 14 final settlements (total of 22 agreements filed); in 2005, there were 3 agreements with restriction on generic entry and compensation to the generic of 11 final settlements (total of 20, for 16 drugs, of agreements filed); and in 2006, 14 out of 28 final settlements had restriction on generic entry and compensation to the generic (total of 45 of agreements filed). Agreements Filed with Federal Trade Commission under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Summary of Agreements Filed in FY 2006, A Report By the Bureau of Competition, Figure III. "In FY 2006, the Commission received . . . more than double the number of agreements received in each of the two previous years." *Id*. at 1.

no settlement at all.[62] Indeed, one of the vocal critics of reverse payment settlements agrees that some settlements simply cannot happen without payments.[63]

There are other crucial questions that need to be answered with empirical evidence before such a sweeping legislation is enacted, particularly given the delicate balance that Hatch-Waxman itself has struck.

For example, when you force more cases to trial, will patent holders win more often than they do now? Perhaps. The current financial incentives of Hatch-Waxman mean that it always makes sense to settle, no matter how strong your patent. If fewer cases settle, a higher percentage of strong patents may be litigated. When settlements dropped off before the 2005 court decisions, at least one empirical analysis showed that the success rate for patentees rose relative to the generics, and actually surpassed it.[64]

Will limitations on the right to settle reduce incentives to innovate and invent? By definition, it would make pharmaceutical patents less valuable. How much? There is no direct evidence, but recall that pharmaceuticals is the one industry where even patent skeptics agree innovation is spurred by the value of patents.[65] The per se ban of

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[62] If that case had settled, it would provide an obvious example where the length of the license is not affected by the fact of the payment. The two license periods proposed were as close together as the parties expectations would allow. The payment did not lengthen the license that would have been granted in its absence because no license would have been granted in its absence. The payment just bridged an otherwise unbridgeable gap in the parties' positions created by the difference in the way they value license length. *See, e.g.*, Marc G. Schildkraut, *Patent-Splitting Settlements and the Reverse Payment Fallacy*, 71 ANTITRUST L.J. 1033, 1060-67 (2004).

[63] *See* Carl Shapiro, *Antitrust Limits to Patent Settlements*, 34 RAND J. OF ECON. 391, 400-01 (Summer 2003) ("We know that joint profits are higher under the agreement than under litigation, . . . so in the absence of any fixed fees, the incumbent captures all of the gains from trade. If we think in terms of Nash bargaining, . . . we would expect the incumbent and entrant to split these gains from trade, which would imply a fixed payment running from the incumbent to the entrant.").

[64] *Gregory Glass, Why Settle?, Update, Sept./Oct. 2005, at 17-19*, (finding that patent holders prevailed in 53 % of all cases decided or settled, while generics prevailed in 47 %).

[65] *See supra* page 11 & n.26.

H.R. 1902 should not be enacted without some assessment of its effect on investments in new drug research.

Will limitations on settlements reduce generic challenges? Quite probably. As noted above, many (including generic companies) believe it will. To maximize these incentives, a generic company should be permitted to choose not only when to commence patent litigation, but also when to terminate it.[66]

What will be the effect of H.R. 1902's changes to Hatch-Waxman's 180-day exclusivity rights? In my view, allowing forfeiture to start from dismissal of any Declaratory Judgment for lack of jurisdiction, as does Section 4, encourages frivolous Declaratory Judgment actions. The subsequent filer is actually better off if the Declaratory Judgment court dismisses the case than if it allows jurisdiction and the second filer has to litigate. This provision would seem to lessen the value of being a first-filer. It would take very little time for a frivolous Declaratory Judgment to be dismissed, and the first-filer may still be litigating. Thus its 180 days would be lost while it was still pursuing litigation. The FTC is currently studying how critical the exclusivity is to first-filer incentives to file challenges, and whether the threat of authorized generics lower those incentives. It would be surpassingly odd for Congress to pass a statute that may harm those incentives far more without awaiting the results of that study.

Finally, if Congress believes that Section 4 of H.R. 1902 eliminates the "bottleneck" issue, what is the need for the rest of the statute? Free entry to a market usually removes any potential for competitive harm. The danger of creating a bottleneck by settling with the first-filer will be over.

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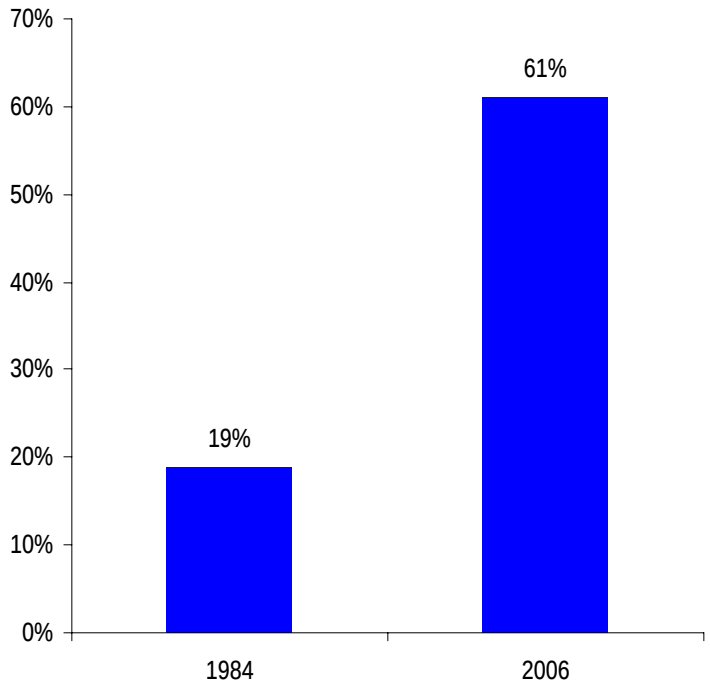
[66] *See, e.g.*, *Cipro*, 261 F. Supp. 2d at 256; *see also supra* pp. 9-11.

V. CONCLUSION

I thank the Chairman and Members of the Committee for inviting me to testify and submit this written statement. I believe that the American public is well served by the Committee's attention to these issues so important to the health and welfare of our Country.

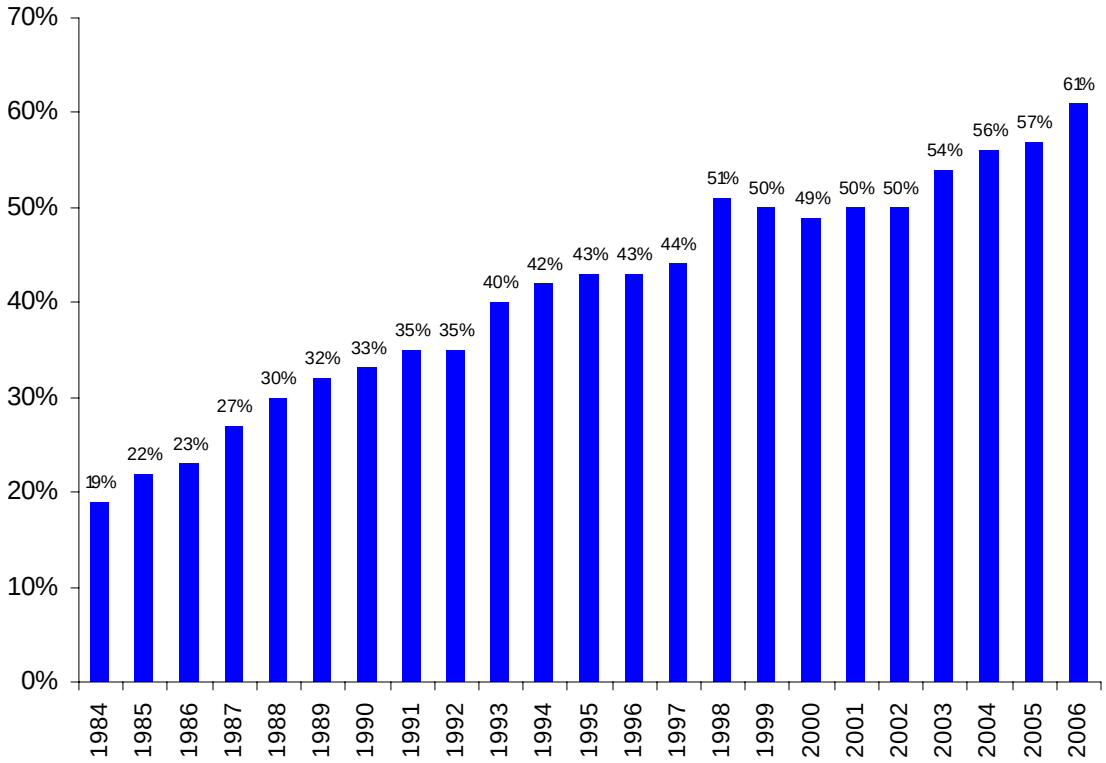
Balancing the twin goals of innovation and invention championed by our system of patents with lower-cost drugs through increased competition due to generic entry is not easy. Congress, through the passage of Hatch-Waxman, and the FTC, through its enforcement efforts, have brought about a dramatic increase in the availability of generic drugs to the American public. While there always will be differences of opinion regarding specific cases, overall Congress' balance between the patent laws and the antitrust laws is working. With the FTC as a vigilant prosecutor, there is no need to create a unique industry specific carve-out from the antitrust laws. Moreover, such a carve-out for specific conduct in a specific industry is contrary to the almost 117 years of reasoned jurisprudence that has and continues to be our antitrust laws.

APPENDIX A



Sources: Deutsche Bank report; 2005: Denske Equities; 2006: Credit

APPENDIX B



Sources: Deutsche Bank report; 2005: Denske Equities; 2006: Credit Suisse